

Correspondence

Educating Physicians for International Health

TO THE EDITOR: The International Health Medical Education Consortium (IHMEC) strongly concurs with Sir Gordon Wolstenholme's call for improving basic health and access to primary health care worldwide to promote self-help, economic independence, and social stability.¹ The case for establishing true primary care for the world's population has long been compelling. Daily, 40,000 children die from ordinary malnutrition and preventable disease and one woman per minute worldwide from problems of pregnancy and childbirth. Despite progress in providing immunizations, devastating shortfalls in basic primary care, safe water and sanitation, primary education and literacy, and safe motherhood remain. The price of closing these gaps is shockingly low—only \$25 billion a year according to UNICEF estimates, compared to the annual outlay of \$50 billion in Europe for cigarettes or \$31 billion in the United States for beer. As little as 3% of all bilateral aid currently goes to primary health care and family planning.

In the United States, the cracks in our primary care system have become evident to rich and poor alike: 37 million Americans are underinsured, and approximately 10% of our children lack a primary care provider. Only 57% of our 2-year-olds are up to date on their immunizations. Moreover, as pointed out by Morgan and Mutalik² at the National Council for International Health, "International health has come home." Official immigration accounted for 30% of population growth in the United States in the 1980s, heightening the disproportionate effect of inadequate primary care falling on the ethnic poor.

Our mission at IHMEC is medical education to improve health and equity in access to health care throughout the world. Our organization was launched in June 1990 to link faculty teaching international health in North American medical schools. We are committed to bringing core skills in primary care and community health assessment for underserved United States and third world communities into the mainstream of US medical training. Our goals are the following:

- Strengthen the teaching of international health at all levels of training, including curriculum development for effective cross-cultural health care.
- Establish an IHMEC network of clinical sites overseas and standards for selection of both trainees and sites.
- Develop stronger career tracks for students, residents, and faculty involved in international health training and programs.
- Provide an ongoing forum for members to share expertise, develop policies, and establish liaison with other organizations interested in international health medical education issues.
- Facilitate collaborative training relationships with students and faculty in foreign medical schools.

Currently IHMEC has over 100 members representing approximately 68 of the 126 medical schools in the United States. Over 200 faculty and health professionals are on IHMEC's mailing list. Membership is open to any faculty member affiliated with a North American medical school. Annual meetings are scheduled to coincide with the meeting of the American Association of Medical Colleges each November.

We would be pleased to join forces with other interested health care professionals both in the United States and abroad.

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False-Positive Human Immunodeficiency Virus Type I ELISA Results in Low-Risk Subjects

TO THE EDITOR: An increasing number of patients with few or no risk factors for human immunodeficiency virus (HIV) infection are asking physicians to screen them for the presence of HIV antibodies. The most commonly used screening method is the enzyme-linked immunosorbent assay (ELISA) test. This test is inexpensive, yet has a relatively high degree of both specificity and sensitivity. We report the results of our recent screening of low-risk healthy subjects who volunteered to participate in research at the University of California, San Diego, using the Organon Vironostika Microelisa Kit (Organon Teknika Corporation, Durham, North Carolina). Although this kit is reported to have a specificity of 98.2% and a false-positive rate of 0.58%, we have received distressingly higher results (manufacturer's package insert). During a ten-month period, 3 of 77 low-risk normal controls had positive ELISA tests. Subsequent Western blot analyses and follow-up ELISA tests were negative. This gives a false-positive rate of about 4%.

Report of Cases

Case 1. The patient, a 38-year-old woman who had had unprotected anal intercourse twice in her life, tested strongly positive for the presence of HIV-1 antibodies. Further questioning revealed that she had had an outbreak of herpes simplex type 2 infection three weeks before her baseline laboratory evaluation.

Case 2. This patient, a 23-year-old man with no known risk factors, tested positive for the presence of

HIV-1 antibodies. A careful review of his medical history revealed that he had been inoculated with the influenza vaccine two months before testing and was having a mild upper respiratory tract infection at the time the initial blood specimen was drawn.

Case 3. The patient, a 32-year-old man, had no known HIV risk factors, but he had received the influenza vaccine two months before HIV testing. He also had had hepatitis C infection several years previously.

These cases illustrate that although the ELISA test may be extremely sensitive, it has varying degrees of specificity. The false-positive ELISA tests in these cases were probably due to cross-reactive immunoglobulin (Ig) M antibodies produced to other viral epitopes. These IgM antibodies may nonspecifically bind to the ELISA microplate and react with anti-idiotypic antibodies to cause a false-positive reaction.

Although positive ELISA tests are routinely confirmed with a Western blot test for the HIV antibody, at our institution (and others) there is frequently a considerable delay from the time that the initial ELISA result is known to when the result of the Western blot test is available. Therefore, as part of the screening of low-risk persons, we now take a careful history specifically asking about recent viral infection and exposure to viral vaccines. Anyone giving such a history we then proactively warn that there is a risk of a false-positive ELISA result. Since instituting this policy six months ago, we have screened another 50 subjects and have had two more false-positive ELISA results; both our and our patients' anxieties were greatly diminished by the proactive discussion.

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Manufacturer Responds

TO THE EDITOR: With regard to Challakere and Rapaport's letter on false-positive ELISA results in low-risk populations, we offer the following response. The Virionostika HIV-1 Microelisa System produced by Organon Teknika Corporation has a specificity claim of 99.96% based on the testing of subjects from a low-risk population (not the 98.2% figure stated in the letter). Despite the manufacturer's attempts to maintain the highest specificity when an HIV test has been pushed as it is for maximum sensitivity, there will be occasions when there are biological false-positives. Supplemental tests are a critical part in testing algorithms to resolve true- from false-positives. For instance, during the 1992 flu vaccine season there were reports of some vaccinee sera that were reactive with HIV ELISA assays but were completely

negative in HIV Western blot assays. Organon Teknika Corporation made presentations at two Food and Drug Administration (FDA) panel advisory boards to discuss this type of false reactivity and to report results on modifications to the VirHIV-1 ELISA test that would eliminate this reactivity and improve specificity. The license amendment for this modified test is under FDA review.

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The Resurgence of Saccharin

TO THE EDITOR: Approximately 60 million adults in the United States complain of indigestion or heartburn at least once a month.^{1(p2)} To treat this potentially lucrative patient base, pharmaceutical companies have introduced a variety of antacid preparations.

Although there has been a plethora of rhetoric on which formula is the best, no comment has been made on the addition of a declared hazardous chemical to these new flavored antacid preparations—sodium saccharin.

While a single tablet or liquid dose contains only a small amount of the sweetener, a recommendation of up to 24 tablets or 12 teaspoons a day over 24 hours must be considered a potential risk factor for long-term use.

In 1977, in compliance with the Delaney Act,² the US Food and Drug Administration (FDA) proposed a ban on saccharin as a food additive because of evidence of carcinogenicity in animals.³ Congressional action blocked the ban and final FDA regulations are still pending.⁴

After a lengthy and stormy national debate, saccharin was removed from most soft drinks, foods, and pharmaceuticals. A total elimination of the product was never accomplished, however. The public continues to be exposed daily to saccharin in a limited number of products such as toothpaste, mouthwashes, thirst quenchers, cold and cough preparations, dietetic foods, and sweeteners.

Even though the government has continued to authorize the restricted use of saccharin, public acceptance and sales have declined in recent years because of health concerns and the introduction of several other thoroughly tested artificial sweeteners. But this trend may be reversing with the introduction of saccharin into newly formulated antacid, analgesic, antidiarrheal, laxative, and cold and cough preparations.

Although federal regulatory codes have mandated that manufacturers place a hazardous substance warning on each saccharin-containing food package and retail establishments must prominently display "saccharin notices" in designated areas, similar notices—which have serious deleterious effects on product merchandising—are not required for non-food or drug items. Why regulators have not demanded that manufacturers use alternative, readily available taste enhancers, especially in tablet forms, also remains a mystery.

As more and more modified-flavor formulas are released, the FDA continues to avoid public comment on